(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
14 June 2001 (14.06.2001)

PCT

(10) International Publication Number
WO 01/41677 A1

(51) International Patent Classification[7]: A61F 2/06

(21) International Application Number: PCT/US00/33369

(22) International Filing Date: 8 December 2000 (08.12.2000)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
09/460,123 13 December 1999 (13.12.1999) US

(71) Applicant: ADVANCED CARDIOVASCULAR SYSTEMS, INC. [US/US]; 3200 Lakeside Drive, Santa Clara, CA 95054-2807 (US).

(72) Inventors: WILSON, W., Stan; 601 W. Spruce, Suite K, Missoula, MT 59802 (US). MAUCH, Kevin, M.; 9463 Victoria Lane, Windsor, CA 95492 (US).

(74) Agents: NAGY, John, S. et al.; Fulwider Patton Lee & Utecht, LLP, Howard Hughes Center, 10th floor, 6060 Center Drive, Los Angeles, CA 90045 (US).

(81) Designated States *(national)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CR, CU, CZ, DE, DK, DM, DZ, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, UZ, VN, YU, ZA, ZW.

(84) Designated States *(regional)*: ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

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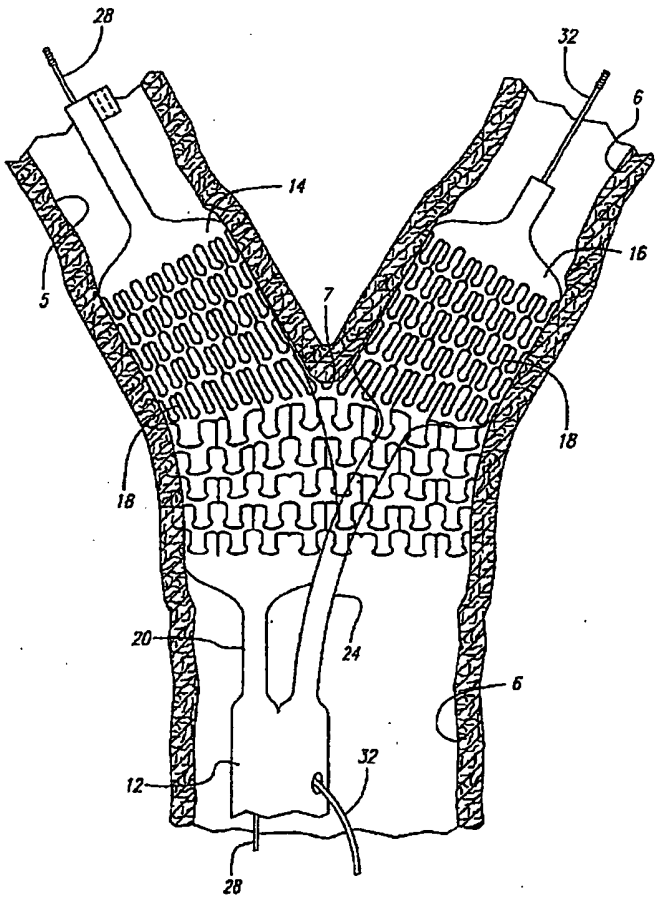
(54) Title: CATHETER ASSEMBLY FOR DELIVERING STENTS



(57) Abstract: An improved catheter assembly and method are provided for treating bifurcated vessels. The catheter assembly of the present invention includes tubular restraint for releasably restraining a pair of balloons during delivery and advancing a bifurcated stent through a vessel. The system is designed for repairing a main vessel and a side branch vessel forming a bifurcation, without compromising blood flow in other portions of the bifurcation, thereby allowing access to all portions of the bifurcated vessel should further interventional treatment be necessary.

WO 01/41677 A1

Published:
— *With international search report.*
— *With (an) indication(s) in relation to deposited biological material furnished under Rule 13bis separately from the description.*

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

CATHETER ASSEMBLY FOR DELIVERING STENTS

BACKGROUND OF THE INVENTION

The invention relates to a catheter assembly for use at a bifurcation and, more particularly, a catheter assembly for implanting a bifurcated stent in a bifurcated blood vessel that is diseased, and a method and apparatus for delivery and implantation.

Stents conventionally repair blood vessels that are diseased. Stents are generally hollow and cylindrical in shape and have terminal ends that are generally perpendicular to their longitudinal axes. In use, the conventional stent is positioned at the diseased area of a vessel and, after placement, the stent provides an unobstructed pathway for blood flow.

Repair of vessels that are diseased at a bifurcation is particularly challenging since the stent must overlay the entire diseased area at the bifurcation, yet not itself compromise blood flow. Therefore, the stent must, without compromising blood flow, overlay the entire circumference of the ostium to a diseased portion and extend to a point within and beyond the diseased portion. Where the stent does not overlay the entire circumference of the ostium to the diseased portion, the stent fails to completely repair the bifurcated vessel. Where the stent overlays the entire circumference of the ostium to the diseased portion, yet extends into the junction comprising the bifurcation, the diseased area is repaired, but blood flow may be compromised in other portions of the bifurcation. Unopposed stent elements may promote lumen compromise during neointimalization and healing, producing restenosis and requiring further procedures. Moreover, by extending into the junction comprising the bifurcation, the stent may block access to portions of the bifurcated vessel that require performance of further interventional procedures. Similar problems are encountered when vessels are diseased at their angled origin from the aorta as in the ostium of a right coronary or a vein graft. In this circumstance, a stent overlaying the entire circumference of the

ostium extends back into the aorta, creating problems, including those for repeat catheter access to the vessel involved in further interventional procedures.

Conventional stents are designed to repair areas of blood vessels that are removed from bifurcations and, since a conventional stent generally terminates at right angles to its longitudinal axis, the use of conventional stents in the region of a vessel bifurcation may result in blocking blood flow of a side branch or fail to repair the bifurcation to the fullest extent necessary. The conventional stent might be placed so that a portion of the stent extends into the pathway of blood flow to a side branch of the bifurcation or extends so far as to completely cover the path of blood flow in a side branch. The conventional stent might alternatively be placed proximal to, but not entirely overlaying, the circumference of the ostium to the diseased portion. Such a position of the conventional stent results in a bifurcation that is not completely repaired. The only conceivable situation in which the conventional stent, having right-angled terminal ends, could be placed where the entire circumference of the ostium is repaired without compromising blood flow, is where the bifurcation is formed of right angles. In such scenarios, extremely precise positioning of the conventional stent is required. This extremely precise positioning of the conventional stent may result in the right-angled terminal ends of the conventional stent overlaying the entire circumference of the ostium to the diseased portion without extending into a side branch, thereby completely repairing the right-angled bifurcation.

To circumvent or overcome the problems and limitations associated with conventional stents in the context of repairing diseased bifurcated vessels, a stent that consistently overlays the entire circumference of the ostium to a diseased portion, yet does not extend into the junction comprising the bifurcation, may be employed. Such a stent would have the advantage of completely repairing the vessel at the bifurcation without obstructing blood flow in other portions of the bifurcation. In addition, such a stent would allow access to all portions of the bifurcated vessel should further interventional treatment be necessary. In a situation involving disease in the origin of an angulated aorto-ostial vessel, such a stent would have the advantage of completely

repairing the vessel origin without protruding into the aorta or complicating repeat access.

In addition to the problems encountered in using the prior art stents to treat bifurcations, the delivery platform for implanting such stents has presented numerous problems. For example, a conventional stent is implanted in the main vessel such that a portion of the stent is across the side branch, so that stenting of the side branch must occur through the main-vessel stent struts. In this method, commonly referred to in the art as the "monoclonal antibody" approach, the main-vessel stent struts must be spread apart to form an opening to the side branch vessel and then a catheter with a stent is delivered through the opening. The cell to be spread apart must be randomly and blindly selected by recrossing the deployed stent with a wire. The drawback with this approach is there is no way to determine or guarantee that the main-vessel stent struts are properly oriented with respect to the side branch or that the appropriate cell has been selected by the wire for dilatation. The aperture created often does not provide a clear opening and creates a major distortion in the surrounding stent struts. There is no way to tell if the main-vessel stent struts have been properly oriented and spread apart to provide a clear opening for stenting the side branch vessel.

In another prior art method for treating bifurcated vessels, commonly referred to as the "Culotte technique," the side branch vessel is first stented so that the stent protrudes into the main vessel. A dilatation is then performed in the main vessel to open and stretch the stent struts extending across the lumen from the side branch vessel. Thereafter, the main-vessel stent is implanted so that its proximal end overlaps with the side branch vessel. One of the drawbacks of this approach is that the orientation of the stent elements protruding from the side branch vessel into the main vessel is completely random. Furthermore, the deployed stent must be recrossed with a wire blindly and arbitrarily selecting a particular stent cell. When dilating the main vessel, stretching the stent struts is therefore random, leaving the possibility of restricted access, incomplete lumen dilatation, and major stent distortion.

In another prior art device and method of implanting stents, a "T" stent procedure includes implanting a stent in the side branch ostium of the bifurcation followed by stenting the main vessel across the side branch ostium. In another prior art procedure, known as "kissing" stents, a stent is implanted in the main vessel with a side branch stent partially extending into the main vessel creating a double-barreled lumen of the two stents in the main vessel proximal to the bifurcation. Another prior art approach includes a so-called "trouser legs and seat" approach, which includes implanting three stents, one stent in the side branch vessel, a second stent in a distal portion of the main vessel, and a third stent, or a proximal stent, in the main vessel just proximal to the bifurcation.

All of the foregoing stent deployment assemblies suffer from the same problems and limitations. Typically, there are uncovered intimal surface segments on the main vessel and side branch vessels between the stented segments. An uncovered flap or fold in the intima or plaque will invite a "snowplow" effect, representing a substantial risk for subacute thrombosis, and the increased risk of the development of restenosis. Further, where portions of the stent are left unopposed within the lumen, the risk for subacute thrombosis or the development of restenosis again is increased. The prior art stents and delivery assemblies for treating bifurcations are difficult to use, making successful placement nearly impossible. Further, even where placement has been successful, the side branch vessel can be "jailed" or covered so that there is impaired access to the stented area for subsequent intervention.

In addition to problems encountered in treating disease involving bifurcations for vessel origins, difficulty is also encountered in treating disease confined to a vessel segment but extending very close to a distal branch point or bifurcation which is not diseased and does not require treatment. In such circumstances, very precise placement of a stent covering the distal segment, but not extending into the ostium of the distal side branch, may be difficult or impossible. The present invention offers a solution to the problems involved in treating bifurcated vessels.

As used herein, the terms "proximal," "proximally," and "proximal direction" when used with respect to the invention are intended to mean moving away from or out of the patient, and the terms "distal," "distally," and "distal direction" when used with respect to the invention are intended to mean moving toward or into the patient. These definitions will apply with reference to apparatus, such as catheters, guide wires, stents, the like. When used with reference to body lumens, such as blood vessels and the like, the terms "proximal," "proximally," and "proximal direction" are intended to mean toward the heart; and the terms "distal," "distally," and "distal direction" are intended to mean away from the heart, and particularly with respect to a bifurcated blood vessel, are intended to mean in the direction in which the branching occurs.

SUMMARY OF THE INVENTION

The invention provides for a catheter assembly for delivering and implanting stents. The system is designed for repairing a main vessel and a side branch vessel forming a bifurcation, without compromising blood flow in other portions of the bifurcation, thereby allowing access to all portions of the bifurcated vessel should further interventional treatment be necessary. The invention also solves problems associated with wire wrapping and tracking over two guide wires.

In one aspect of the invention, there is provided a stent delivery assembly for implanting a Y-shaped stent in a bifurcated vessel having a first vessel branch and a second vessel branch. A dual balloon Y-shaped catheter is provided including a first expandable member having a proximal end and a distal end, a second expandable member having a proximal end and a distal end, a main catheter body, a first catheter branch connecting the first expandable member to the main catheter body, and a second catheter branch connecting the second expandable member to the main catheter body. A first guide wire lumen is included for receiving a first guide wire. The first guide wire lumen extends through at least a portion of the catheter including the first

expandable member. A second guide wire lumen is provided for receiving a second guide wire. The second guide wire lumen extends through at least a portion of the catheter including the second expandable member. The first expandable member and the second expandable member are normally biased apart, but are restrained and held together to provide a low profile during delivery of a Y-shaped stent.

In another aspect of the invention, there is provided a method of stenting a bifurcated vessel having a bifurcation with a carina, a first vessel branch, and a second vessel branch. A dual balloon Y-shaped catheter is provided including a first expandable member having a proximal end and a distal end, a second expandable member having a proximal end and a distal end, a main catheter body, a first catheter branch connecting the first expandable member to the main catheter body, and a second catheter branch connecting the second expandable member to the main catheter body. The first expandable member is longer than the second expandable member. The first expandable member and the second expandable member are normally biased apart, but are restrained and held together to provide a low profile during delivery of a Y-shaped stent.

A first guide wire lumen is provided for receiving a first guide wire. The first guide wire lumen extends through at least a portion of the catheter including the first expandable member. A second guide wire lumen is provided for receiving a second guide wire. The second guide wire lumen extends through at least a portion of the catheter including the second expandable member. A Y-shaped stent is mounted on the first and second expandable members. A second guide wire is positioned such that it extends within the first vessel branch proximally of the bifurcation and within the second vessel branch distally of the bifurcation. The catheter can then be advanced distally over the second guide wire via the second guide wire lumen so that the distal end of the first expandable member is advanced distally of the bifurcation in the second vessel branch, wherein the second expandable member is positioned into apposition with the bifurcation. The catheter is then positioned such that the distal end of the first expandable member is just distal of the carina in the second vessel branch.

A first guide wire is advanced distally out of the first guide wire lumen and into the second vessel branch. The second guide wire is withdrawn proximally such that the first and second expandable members are released and spring apart. The second guide wire is then advanced distally in the first vessel branch. The first guide wire can then be further advanced distally in the second vessel branch. The catheter is then advanced distally over the first and second guide wires until the Y-shaped stent is positioned at the bifurcation. The Y-shaped stent can be implanted by inflating the first and second expandable members. The first and second expandable members are then deflated.

Other features and advantages of the present invention will become apparent from the following detailed description, taken in conjunction with the accompanying drawings, which illustrate, by way of example, the principles of the invention.

BRIEF DESCRIPTION OF THE DRAWINGS

FIGURE 1 is an elevational view of a bifurcation in which a prior art "T" stent is in a side branch ostium followed by the stenting of the main vessel across the branch ostium.

FIG. 2 is an elevational view of a bifurcation in which "touching" prior art stents are depicted in which one stent is implanted in the side branch, a second stent implanted in a distal portion of the main vessel next to the branch stent, with interrupted placement of a third stent implanted more proximally in the main vessel.

FIG. 3 is an elevational view of a bifurcation depicting "kissing" stents where a portion of one stent is implanted in both the side branch and the main vessel and adjacent to a second stent implanted in the main vessel creating a double-barreled lumen in the main vessel proximal to the bifurcation.

FIG. 4 is an elevational view of a prior art "trouser legs and seat" stenting approach depicting one stent implanted in the side branch vessel, a second stent implanted in a proximal portion of the main vessel, and a close deployment of a third stent distal to the bifurcation leaving a small gap between the three stents of an uncovered lumenal area.

FIG. 5A is an elevational view of a bifurcation in which a prior art stent is implanted in the side branch vessel.

FIG. 5B is an elevational view of a bifurcation in which a prior art stent is implanted in the side branch vessel, with the proximal end of the stent extending into the main vessel.

FIG. 6 is an elevational view, partially in section, depicting an embodiment of a Y-shaped catheter assembly for deploying a Y-shaped stent in a bifurcation.

FIG. 7 is an elevational view, partially in section, depicting the Y-shaped catheter assembly of FIG. 6 in which expandable members are restrained and held together.

FIG. 8 is an elevational view, partially in section, depicting a guide wire at a bifurcation.

FIG. 9 is an elevational view, partially in section, of a bifurcation in which the catheter of FIG. 6 is delivering the stent in the bifurcated area, tracking over the wire that joins the two expandable members together.

FIG. 10 is an elevational view, partially in section, of a bifurcation in which the distal end of an expandable member of the catheter of FIG. 6 is just distal to the carina.

FIG. 11 is an elevational view, partially in section, of a bifurcation in which the expandable members of the catheter of FIG. 6 have been released.

FIG. 12 is an elevational view, partially in section, in which the Y-shaped stent is in apposition with the carina.

FIG. 13 is an elevational view, partially in section, in which the expandable members of the catheter of FIG. 6 are in an expanded condition.

FIG. 14 is an elevational view, partially in section, in which the Y-shaped stent has been implanted at the bifurcation and the catheter and guide wires of FIG. 6 have been removed.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

As shown in the exemplary drawings wherein like reference numerals indicate like or corresponding elements among the figures, the present invention includes a stent delivery system for treating bifurcated vessels in, for example, the coronary arteries, veins, arteries, and other vessels in the body.

Prior art attempts at implanting intravascular stents in a bifurcation have proved to be less than satisfactory. For example, FIGS. 1-4 depict prior art devices which include multiple stents being implanted in both the main vessel and a side branch vessel. In FIG. 1, a prior art "T" stent is implanted such that a first stent is implanted in the side branch near the ostium of the bifurcation, and a second stent is implanted in the main vessel, across the side branch ostium. With this approach,

portions of the side branch vessel are left uncovered, and blood flow to the side branch vessel must necessarily pass through the main vessel stent, causing possible obstructions or thrombosis.

Referring to FIG. 2, three prior art stents are required to stent the bifurcation. In FIG. 3, the prior art method includes implanting two stents side by side, such that one stent extends into the side branch vessel and the main vessel, and the second stent is implanted in the main vessel. This results in a double-barreled lumen which can present problems such as thrombosis, and turbulence in blood flow. Referring to the FIG. 4 prior art device, a first stent is implanted in the side branch vessel, a second stent is implanted in a proximal portion of the main vessel, and a third stent is implanted distal to the bifurcation, thereby leaving a small gap between the stents and an uncovered lumenal area.

Referring to FIGS. 5A and 5B, a prior art stent is configured for deployment in side branch vessel 5. In treating side branch vessel 5, if a prior art stent is used, a condition as depicted will occur. That is, a stent deployed in side branch vessel 5 will leave a portion of the side branch vessel exposed, or as depicted in 5B, a portion of the stent will extend into main vessel 6.

Turning to FIGS. 6 and 7, in one embodiment of the present invention, stent delivery assembly 10 is provided for treating bifurcated vessels. In this embodiment, a Y-shaped stent is implanted to cover the bifurcation. Catheter 12 can be configured as a dual balloon Y-shaped catheter. The catheter includes first expandable member 14 and second expandable member 16 that are configured to reside side-by-side (Y-shaped) for low profile delivery and to spring apart for implanting Y-shaped stent 18. Each of the expandable members has a proximal end and a distal end. The stent can be removably mounted on the first and second expandable members.

The catheter 12 further includes main catheter body 20. A first catheter branch 22 connects first expandable member 14 to the main catheter body. A second catheter branch 24 connects second expandable member 16 to the main catheter body.

A first guide wire lumen 26 is provided for receiving first guide wire 28. In this embodiment, the first guide wire lumen is of the over-the-wire (OTW) type, which is known in the art; however, it is contemplated that the first guide wire lumen can be of the rapid-exchange (RX) type or unzippable-rapid-exchange type, which are also known in the art. The first guide wire lumen extends through at least a portion of catheter 12 including first expandable member 14.

A second guide wire lumen 30A, 30B is provided for receiving second guide wire 32. In this embodiment, the second guide wire lumen is of the rapid-exchange type; however, it is contemplated the second guide wire lumen can be of the unzippable-rapid-exchange type or over-the-wire type. The second guide wire lumen extends through at least a portion of the catheter including second expandable member 16. The expandable members can be inflatable non-distensible balloons. The guide wires 28,32 preferably are stiff wires each having a diameter of 0.014 inch, but can have different diameters and degrees of stiffness as required for a particular application. A particularly suitable guide wire can include those manufactured and sold under the tradenames Sport® and Ironman®, manufactured by Advanced Cardiovascular Systems, Incorporated, Santa Clara, California.

The first expandable member 14 and second expandable member 16 are normally biased apart, but can be restrained and held together to provide a low profile during delivery of Y-shaped stent 18. The expandable members can be held together by positioning second guide wire 32 through second guide wire lumen 30A that runs through the second expandable member and second guide wire lumen 30B that runs through tubular restraint 34. The tubular restraint is attached to distal end 36 of the first expandable member. Alternatively, lumen 30B can run through distal end 36. The distal end of the first expandable member protrudes distally of the distal end of the second expandable member to facilitate tracking over second guide wire 32. The distal end of the first expandable member can include a radiopaque marker for facilitating delivery in the body.

The catheter 12 further includes an inflation lumen (not shown) for inflating first and second expandable members 14, 16 simultaneously. The expandable members can be inflated by delivering a suitable inflation media, such as saline, to the expandable members via the inflation lumen. In this embodiment, the first expandable member is approximately twice as long as the second expandable member; however, it is contemplated that the first and second expandable members may have varying lengths.

In one method of stenting a bifurcated vessel, as shown in FIGS. 8-14, Y-shaped stent 18 is mounted on first and second expandable members 14,16. The second guide wire 32 (or tracking guide wire) is positioned such that it extends within first vessel branch 6 (such as a main vessel) proximally of the bifurcation and within second vessel branch 5 (such as a side-branch vessel) distally of the bifurcation. The catheter 12 is then advanced distally over the second guide wire via second guide wire lumen 30A,30B so that the distal end of first expandable member 14 is advanced distally of the bifurcation in the second vessel branch. If assembly 10 arrives with the first expandable member more proximate carina 7 than second expandable member 16, the first expandable member will encounter the vessel wall proximate the carina. It is intended that this scenario will produce a tendency for the assembly to rotate as the second guide wire continues to appose the vessel wall proximate the carina. Therefore, the second expandable member 16 is positioned into apposition with the bifurcation at the carina. If necessary, the known technique of visual assignment of the guide wires can be implemented. In this case, the wires can include visible portions for identification on highly magnified fluoroscopy.

After rotation of assembly 10 has occurred, catheter 12 is positioned such that distal end 36 of first expandable member 14 is just distal of carina 7 in second vessel branch 5. Up until this point, it is contemplated that first guide wire 28 (or the integrated guide wire) can reside within first guide wire lumen 26. Alternatively, the first guide wire can now be inserted into the proximal end of the first guide wire lumen. Subsequently, the first guide wire is advanced distally out of the first guide

wire lumen and into the second vessel branch. The second guide wire 32 can then be withdrawn proximally and out of lumen 30B. This action causes the first and second expandable members to be released and spring apart into a relaxed condition. The distance that the first and second expandable members spring apart may be very small and can vary depending on the application. It is also contemplated that the catheter can be designed such that when the first and second expandable members are released they do not spring apart at all.

Next, second guide wire 32 is advanced distally in first vessel branch 6. The first guide wire 28 can then be further advanced distally in second vessel branch 5. The catheter 12 is now advanced distally over the first and second guide wires until Y-shaped stent 18 is positioned at the bifurcation (*i.e.*, anchored at carina 7). The stent can now be anchored by inflating the first and second expandable members 14,16. The first and second expandable members can now be deflated and the catheter and guide wires can be withdrawn from the patient's vasculature. The novel arrangement of guide wires 28,32 and their respective lumens permit single unit transport of a Y-shaped stent to the distal target site without wire wrapping problems and it allows for minimal requirements of rotation of the device (less than 90 degrees) for optimal deployment (allowing minimal twist deformity). It is contemplated that the guide wires can be left in their respective vessels should sequential or simultaneous high pressure balloon inflation be required in each of the vessels in order to complete the stenting procedure. This additional step is a matter of physician choice.

Thus, Y-shaped stent 18 is delivered to a bifurcation in a manner that reduces the chances of wire wrapping and crossing. Notably, it is contemplated that the methods of the present invention can be accomplished with suitable variations of catheter 12.

While the invention herein has been illustrated and described in terms of a catheter assembly and method of use, it will be apparent to those skilled in the art that the invention can be used in other instances. Other modifications and improvements may be made without departing from the scope of the invention.

5. The assembly of claim 1, further including an inflation lumen for inflating the first and second expandable members.

6. The assembly of claim 5, wherein the first and second expandable members inflate simultaneously.

7. The assembly of claim 1, wherein when the first expandable member and the second expandable member are restrained and held together and the distal end of the first expandable member is distal of the distal end of the second expandable member.

8. The assembly of claim 2, wherein the distal end of the first expandable member includes a radiopaque marker.

9. A method of stenting a bifurcated vessel having a bifurcation, a first vessel branch, and a second vessel branch, comprising the steps of:

providing a dual balloon Y-shaped catheter including a first expandable member having a proximal end and a distal end, a second expandable member having a proximal end and a distal end, a main catheter body, a first catheter branch connecting the first expandable member to the main catheter body, and a second catheter branch connecting the second expandable member to the main catheter body;

wherein the first expandable member and the second expandable member are normally biased apart, but are restrained and held together to provide a low profile during delivery of a Y-shaped stent;

providing a Y-shaped stent mounted on the first and second expandable members;

providing a first guide wire lumen for receiving a first guide wire, the first guide wire lumen extending through at least a portion of the catheter including the first expandable member; and

providing a second guide wire lumen for receiving a second guide wire, the second guide wire lumen extending through at least a portion of the catheter including the second expandable member;

delivering the Y-shaped stent to a target area;

releasing the first expandable member from the second expandable member such that they spring apart;

implanting the Y-shaped stent by inflating the first and second expandable members; and

deflating the first and second expandable members.

10. A method of stenting a bifurcated vessel having a bifurcation with a carina, a first vessel branch, and a second vessel branch, comprising the steps of:

providing a dual balloon Y-shaped catheter including a first expandable member having a proximal end and a distal end, a second expandable member having a proximal end and a distal end, a main catheter body, a first catheter branch connecting the first expandable member to the main catheter body, and a second catheter branch connecting the second expandable member to the main catheter body;

wherein the first expandable member is longer than the second expandable member, and wherein the first expandable member and the second expandable member are normally biased apart, but are restrained and held together to provide a low profile during delivery of a Y-shaped stent;

providing a first guide wire lumen for receiving a first guide wire, the first guide wire lumen extending through at least a portion of the catheter including the first expandable member;

providing a second guide wire lumen for receiving a second guide wire, the second guide wire lumen extending through at least a portion of the catheter including the second expandable member;

providing a Y-shaped stent mounted on the first and second expandable members;

providing a second guide wire and positioning it such that it extends within the first vessel branch proximally of the bifurcation and within the second vessel branch distally of the bifurcation;

advancing the catheter distally over the second guide wire via the second guide wire lumen so that the distal end of the first expandable member is advanced distally of the bifurcation in the second vessel branch, wherein the second expandable member is positioned into apposition with the bifurcation;

positioning the catheter such that the distal end of the first expandable member is just distal of the carina in the second vessel branch;

providing a first guide wire and advancing the first guide wire distally out of the first guide wire lumen and into the second vessel branch;

withdrawing the second guide wire proximally such that the first and second expandable members are released and spring apart;

advancing the second guide wire distally in the first vessel branch;

further advancing the first guide wire distally in the second vessel branch;

advancing the catheter distally over the first and second guide wires until the Y-shaped stent is positioned at the bifurcation;

implanting the Y-shaped stent by inflating the first and second expandable members; and

deflating the first and second expandable members.

FIG. 1
PRIOR ART

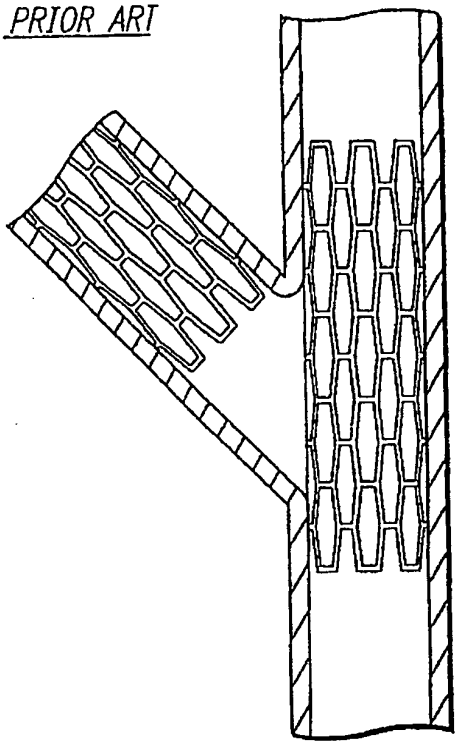


FIG. 2
PRIOR ART

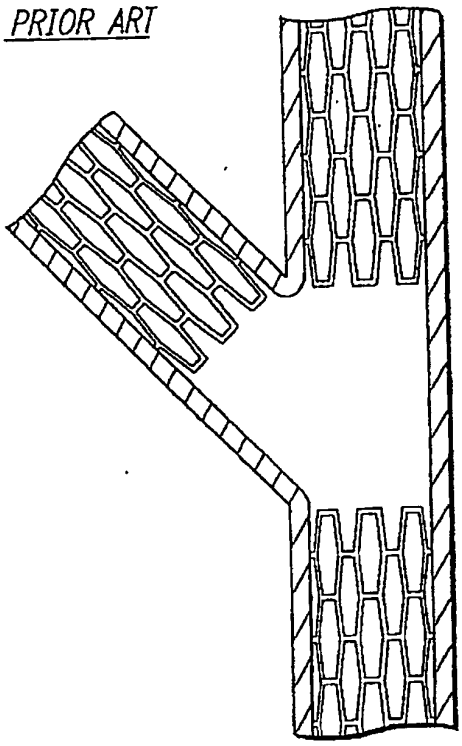


FIG. 3
PRIOR ART

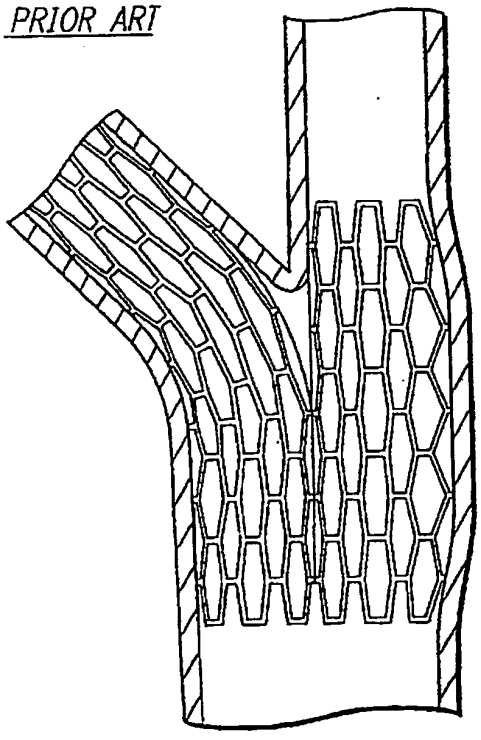


FIG. 4
PRIOR ART

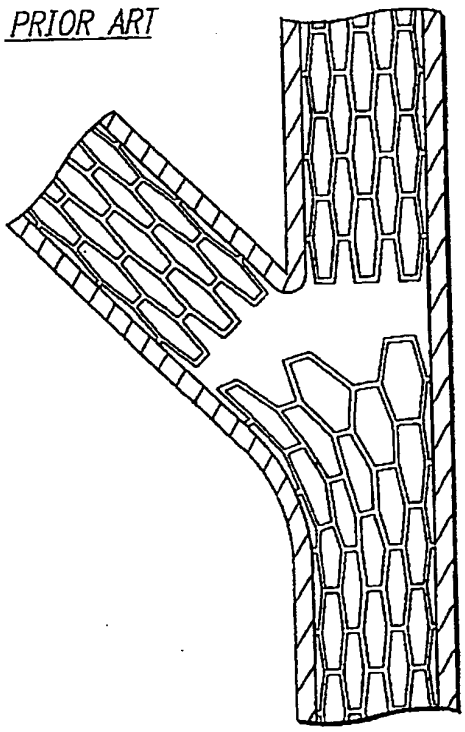
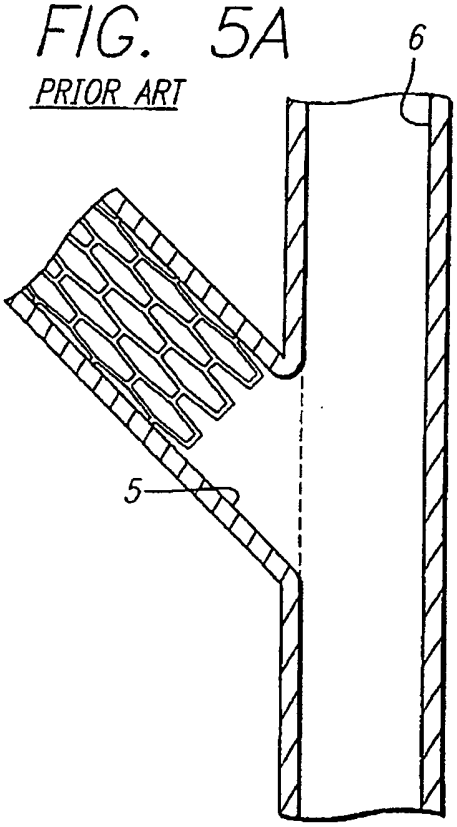


FIG. 5A
PRIOR ART



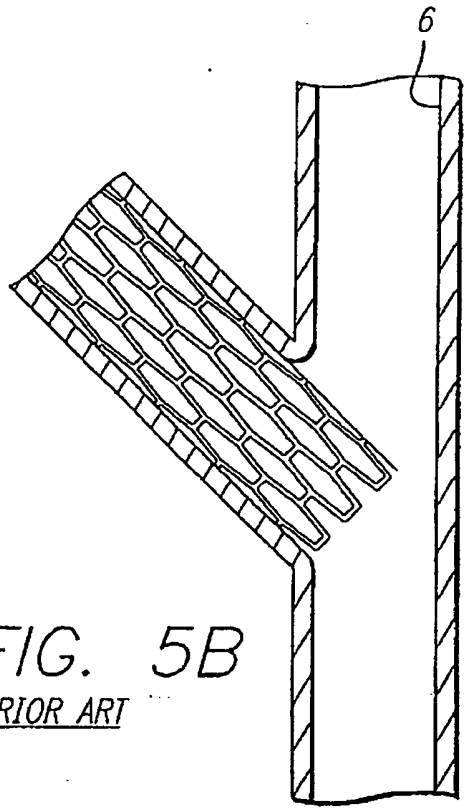


FIG. 5B
PRIOR ART

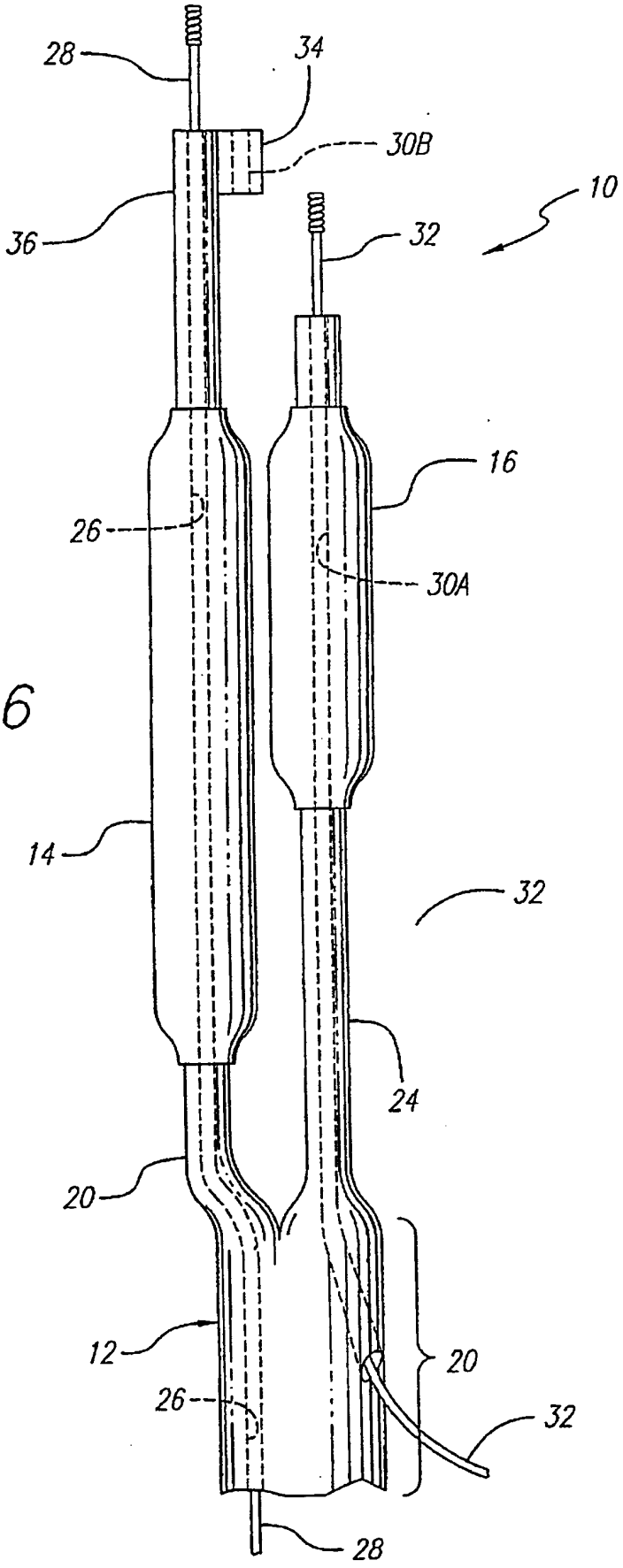


FIG. 6

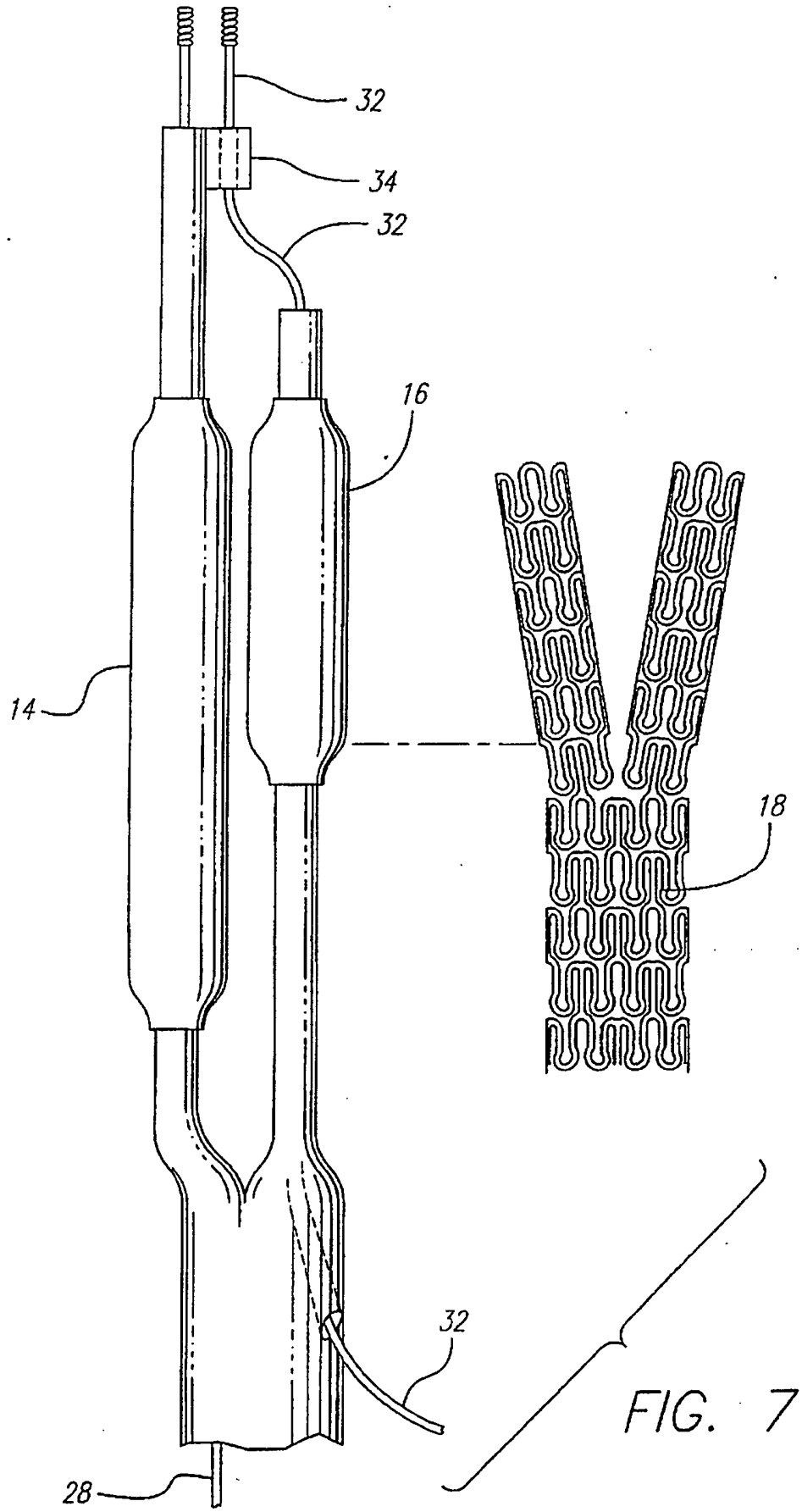


FIG. 7

FIG. 8

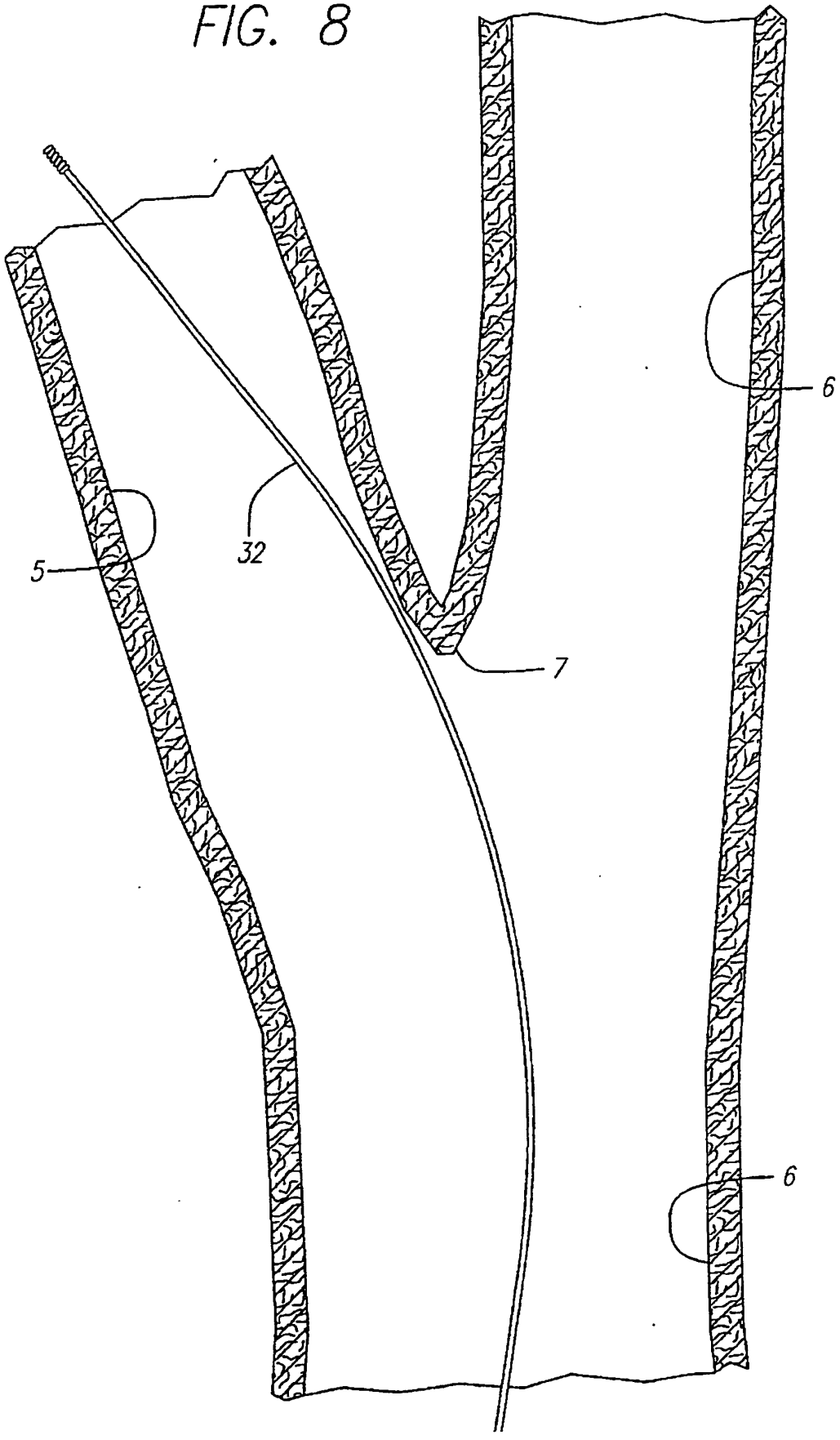
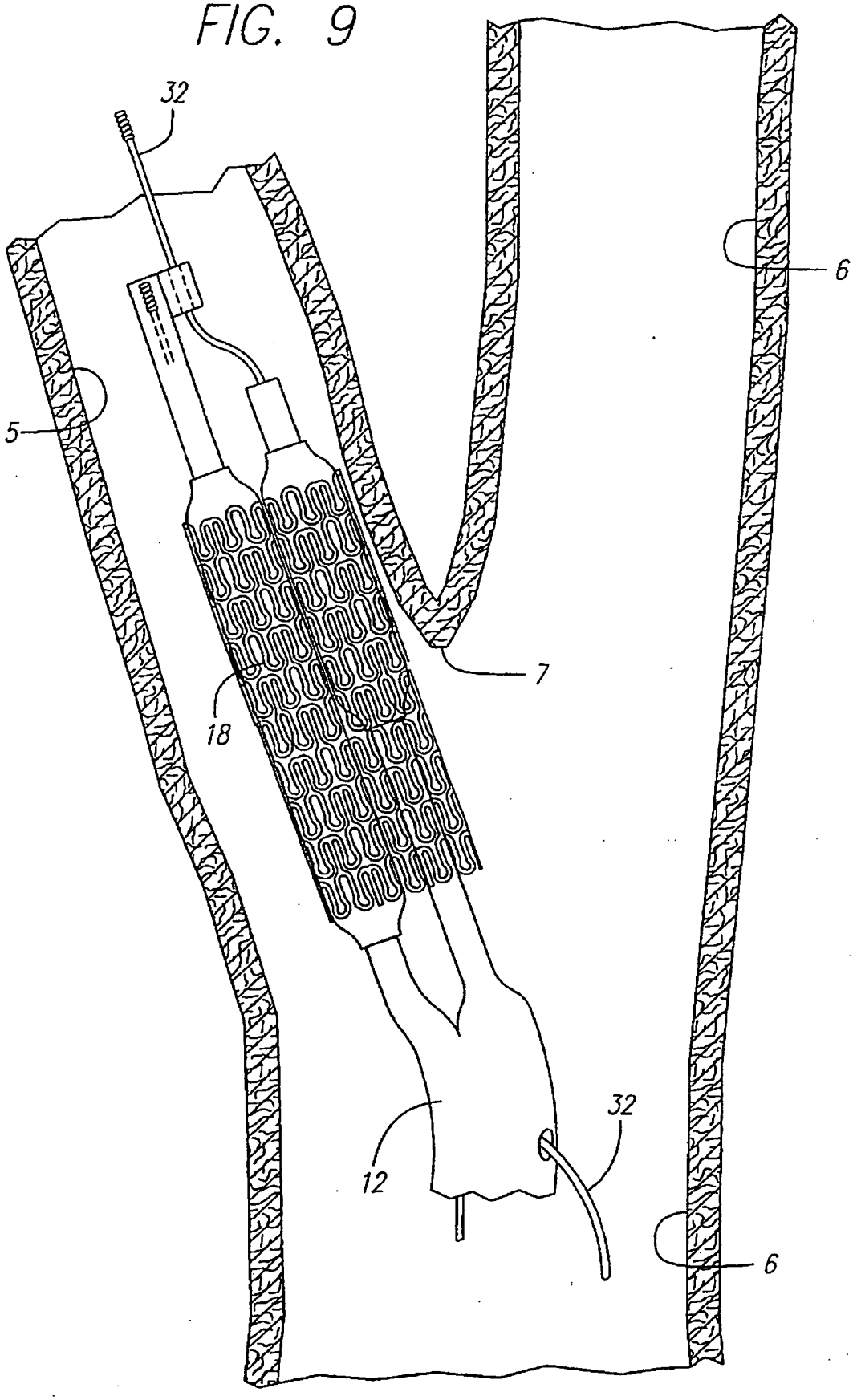


FIG. 9



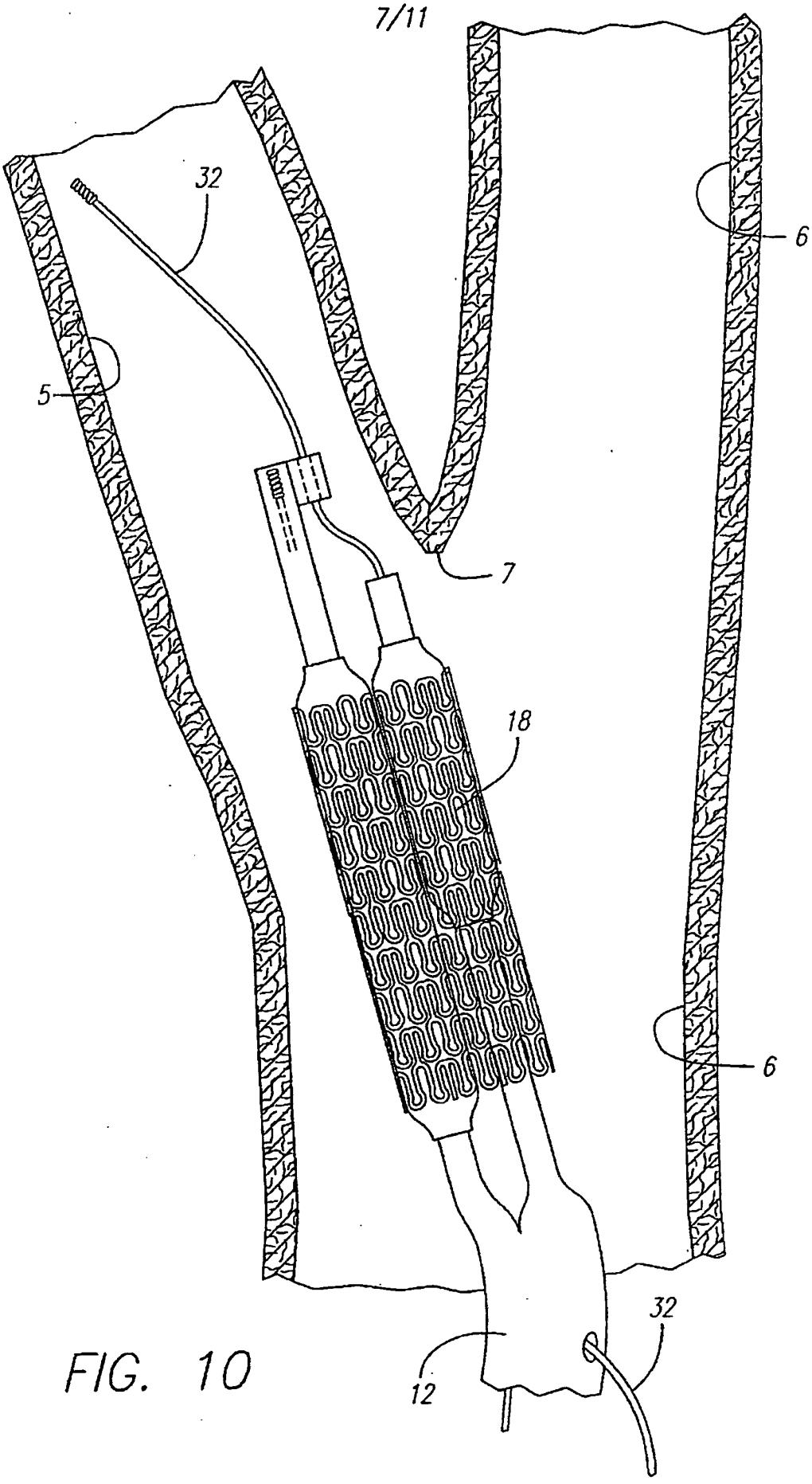


FIG. 10

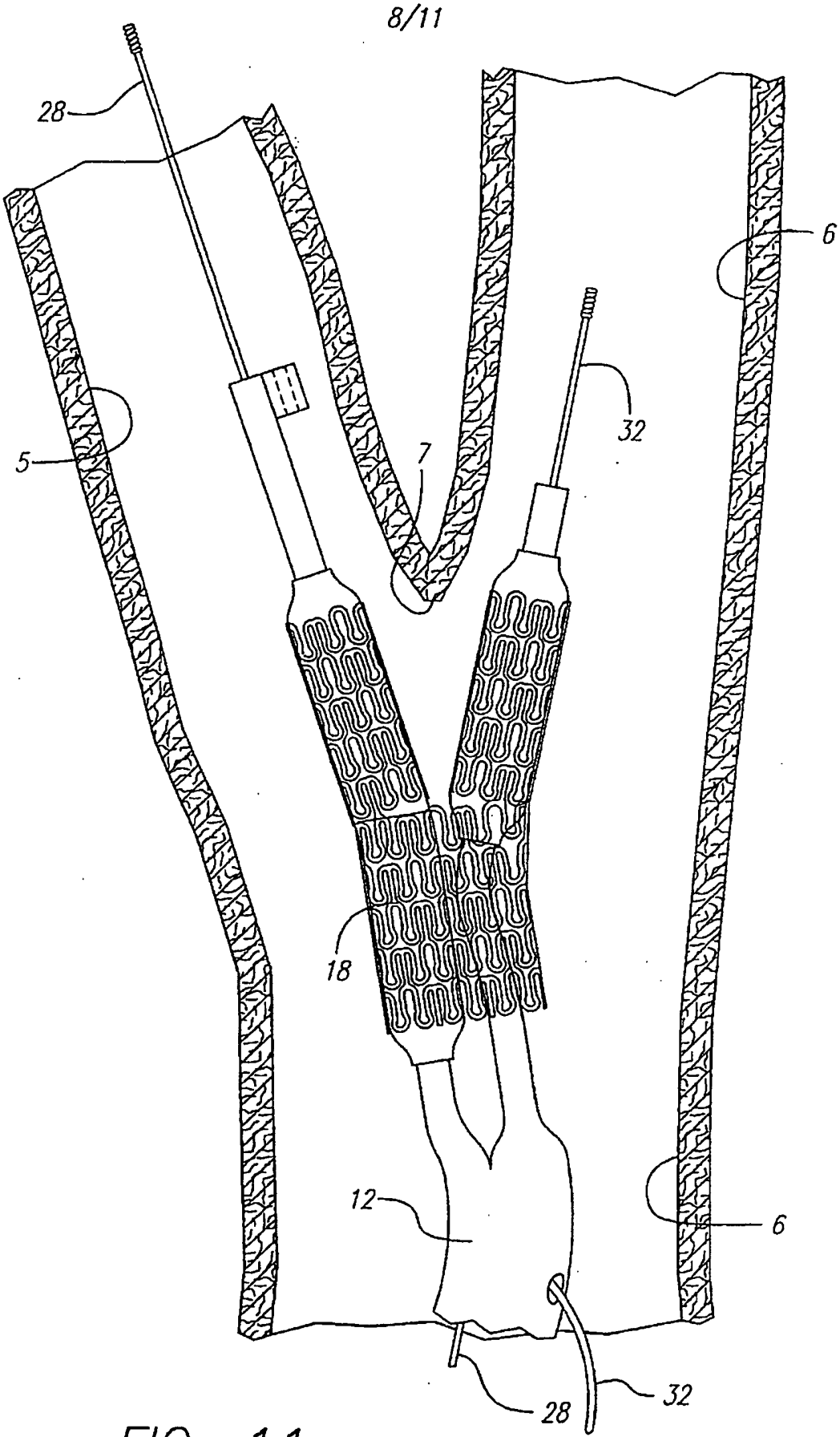


FIG. 11

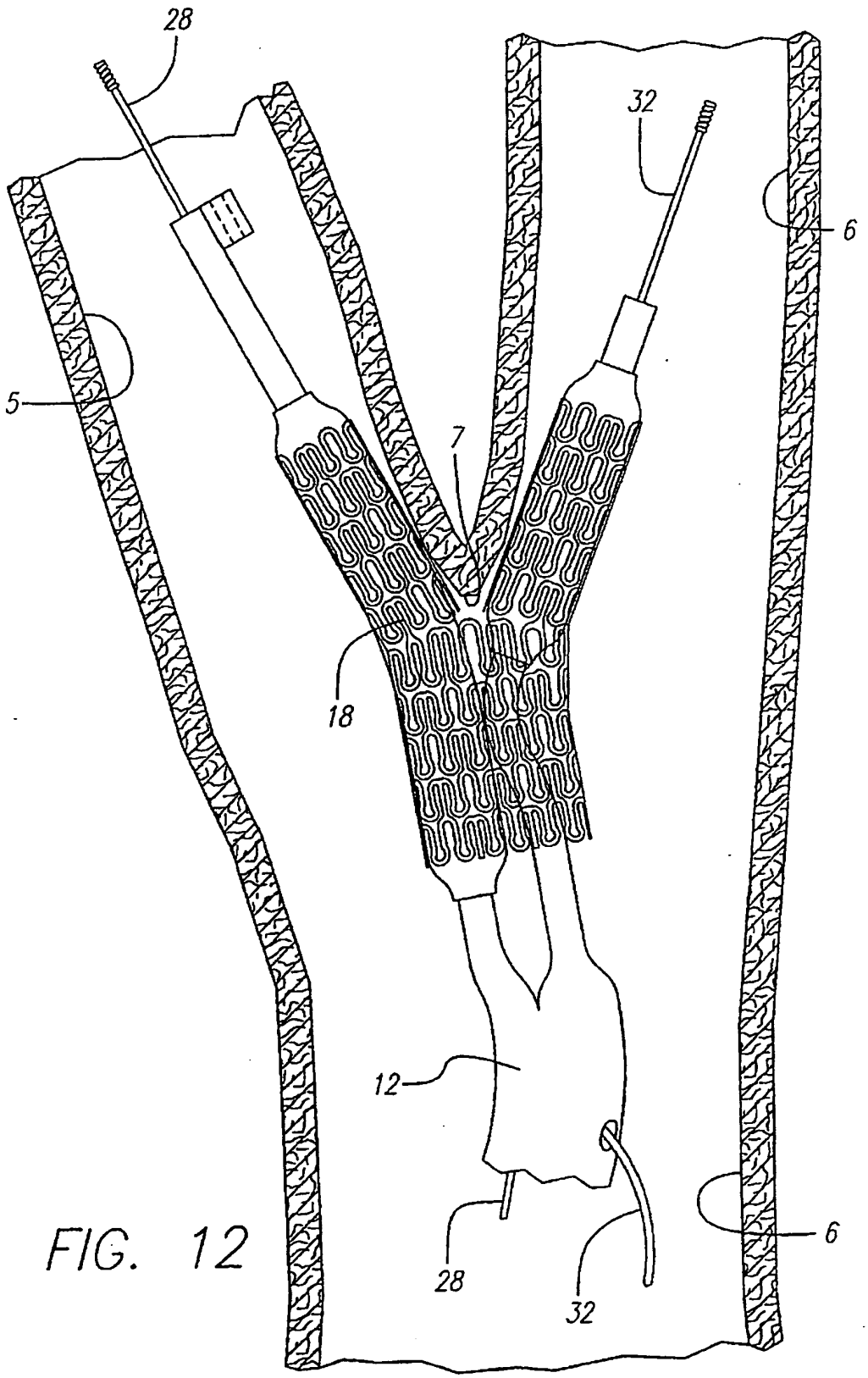


FIG. 12

FIG. 13

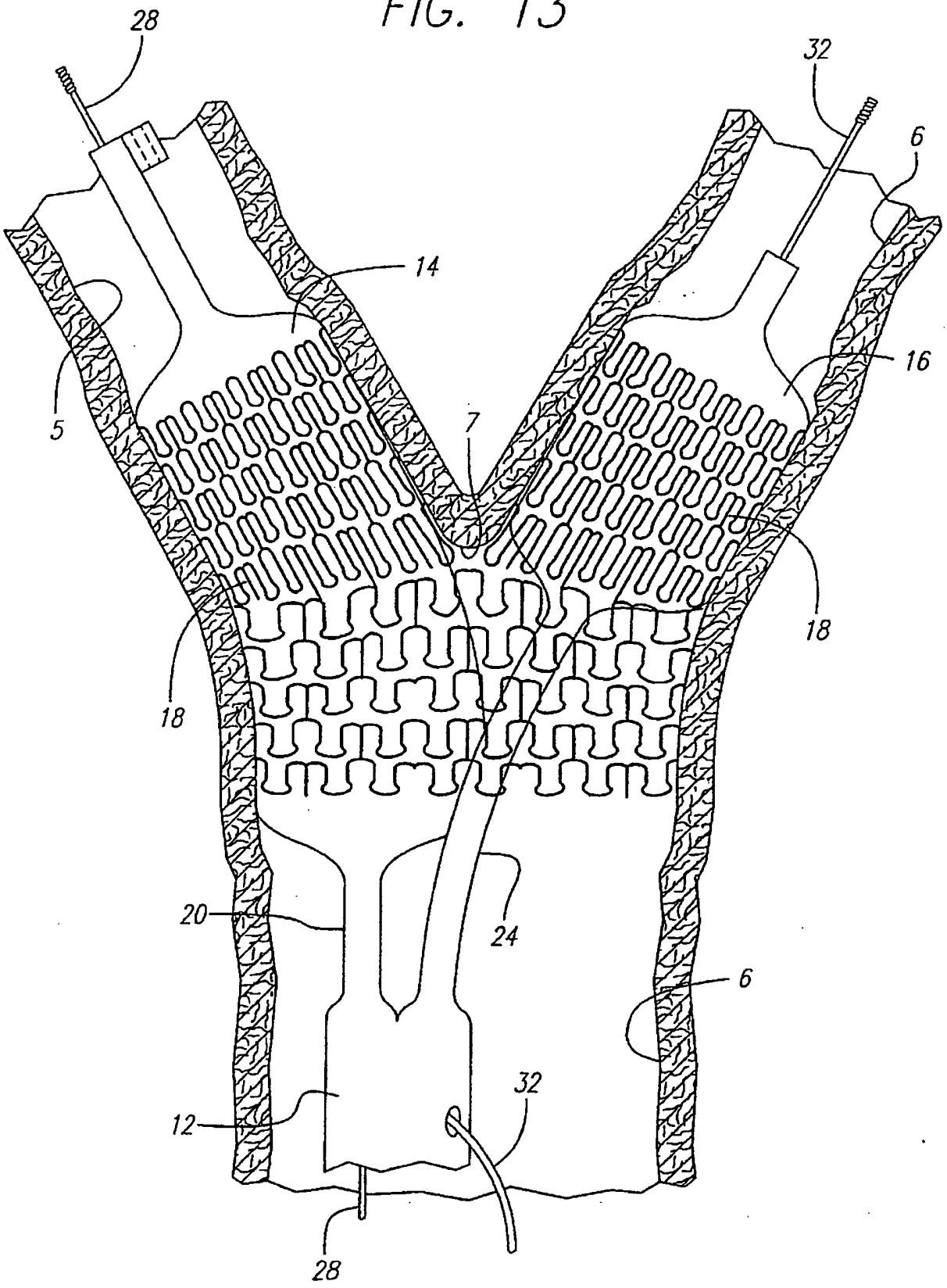
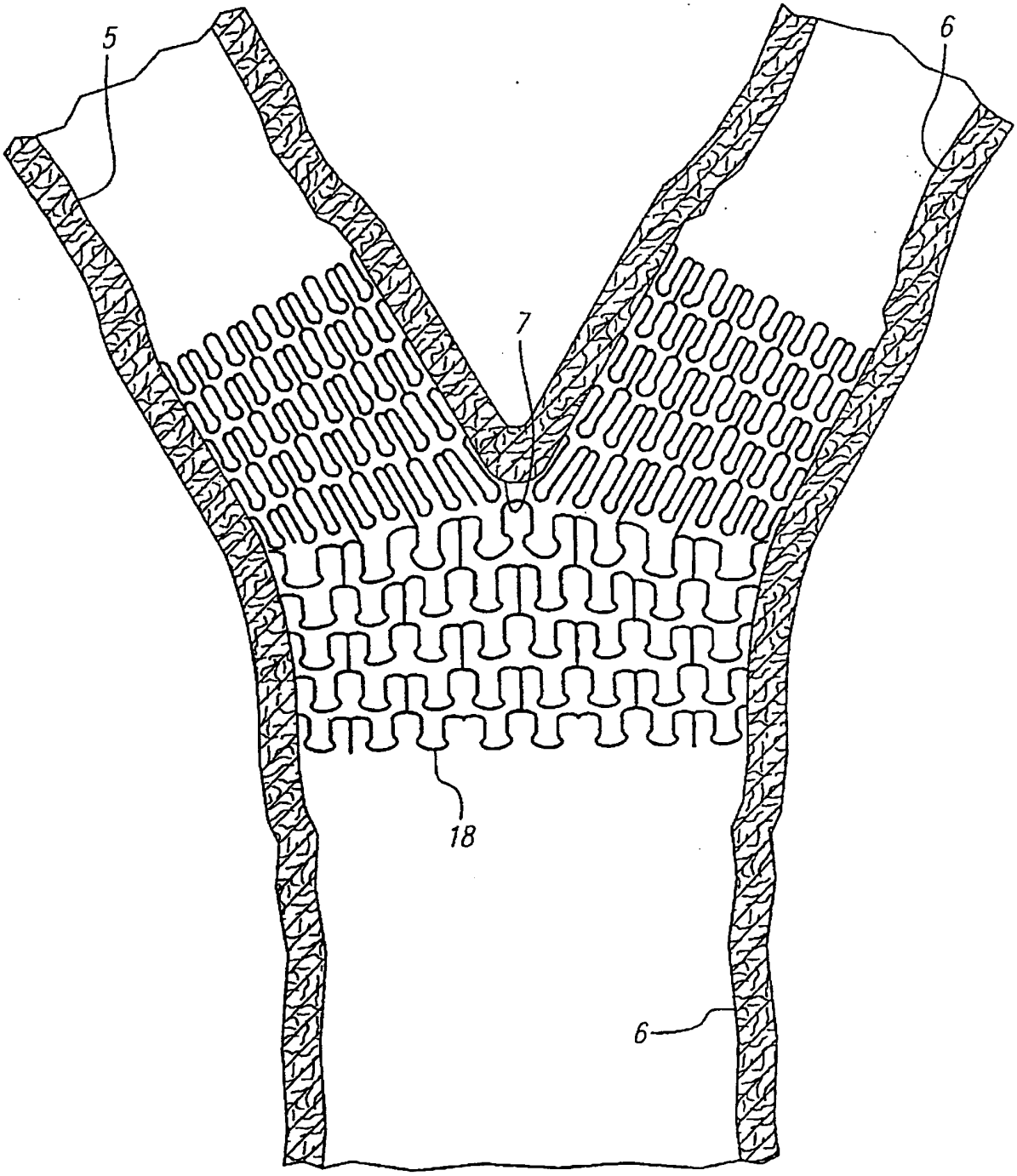


FIG. 14



INTERNATIONAL SEARCH REPORT

Ir. stional Application No
PCT/US 00/33369

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61F2/06

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
WPI Data, EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 0 897 700 A (ADVANCED CARDIOVASCULAR SYSTEMS, INC.) 24 February 1999 (1999-02-24) column 29, line 58 -column 30, line 17; figures 27-33	1,4-6
A	US 5 755 771 A (PENN ET AL) 26 May 1998 (1998-05-26) column 6, line 59 -column 7, line 41; figures 5-7	1
A	WO 99 04726 A (ZIMARINO) 4 February 1999 (1999-02-04)	

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

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Date of the actual completion of the international search	Date of mailing of the international search report
28 February 2001	07/03/2001

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Smith, C

Information on patent family members

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